Overview

Useful For
Determining a patient’s immunological response to diphtheria toxoid vaccination
Aiding in the evaluation of immunodeficiency

Method Name
Enzyme-Linked Immunosorbent Assay (ELISA)

NY State Available
Yes

Specimen

Specimen Type
Serum

Specimen Required

Container/Tube:
Preferred: Serum gel
Acceptable: Red top

Specimen Volume: 0.5 mL

Forms
If not ordering electronically, complete, print, and send a Microbiology Test Request (T244) with the specimen.

Reject Due To

Gross hemolysis Reject
Gross lipemia Reject
Gross icterus Reject
Heat inactivated specimen Reject

Specimen Minimum Volume
0.4 mL

Specimen Stability Information

<table>
<thead>
<tr>
<th>Specimen Type</th>
<th>Temperature</th>
<th>Time</th>
<th>Special Container</th>
</tr>
</thead>
<tbody>
<tr>
<td>Serum</td>
<td>Refrigerated (preferred)</td>
<td>30 days</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Frozen</td>
<td>30 days</td>
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</table>

Clinical & Interpretive
**Clinical Information**

Diphtheria is an acute, contagious, febrile illness caused by the bacterium *Corynebacterium diphtheriae*. The disease is classically characterized by a combination of localized inflammation in the upper respiratory tract with the formation of a diphtheric pseudomembrane over the oropharynx, including the tonsils, pharynx, larynx and posterior nasal passages. *C diphtheriae* produces a potent diphtheria exotoxin that is absorbed systemically and can lead to cardiac failure and paralysis of the diaphragm. The disease is preventable by vaccination with diphtheria toxoid, which stimulates antidiphtheria toxoid antibodies. In the United States, diphtheria toxoid is administered to children as part of the combined diphtheria, tetanus, and acellular pertussis (TDaP) vaccine. A patient’s immunological response to diphtheria toxoid vaccination can be determined by measuring antidiphtheria toxoid IgG antibody using this enzyme immunoassay technique. An absence of antibody formation postvaccination may relate to immune deficiency disorders, either congenital or acquired, or iatrogenic due to immunosuppressive drugs.

**Reference Values**

Vaccinated: Positive (≥0.01 IU/mL)
Unvaccinated: Negative (<0.01 IU/mL)
Reference values apply to all ages.

**Interpretation**

Results of 0.01 IU/mL or more suggest a vaccine response.

A diphtheria toxoid booster should be considered for patients with antidiphtheria toxoid IgG values between 0.01 and less than 0.1 IU/mL.

**Cautions**

This assay does not provide diagnostic proof of lack of protection against diphtheria or the presence of absence of immunodeficiency. Results must be confirmed by clinical findings and other serological tests.

**Supportive Data**

<table>
<thead>
<tr>
<th></th>
<th>Comparison of the EuroImmun and Binding Site Anti-Diphtheria Toxoid IgG ELISAs</th>
<th>Binding Site IgG ELISA</th>
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<tbody>
<tr>
<td></td>
<td>Positive</td>
<td>Negative</td>
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<tr>
<td>Total</td>
<td>EuroImmun IgG ELISA</td>
<td>Positive</td>
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<tr>
<td>206</td>
<td>0</td>
<td>206</td>
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<tr>
<td>Negative</td>
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</table>

**Clinical Reference**

Test Definition: DIPGS
Diphtheria Toxoid IgG Ab, S


Performance

Method Description
The EuroImmun Anti-Diphtheria Toxoid IgG enzyme-linked immunosorbent assay (ELISA) kit provides a quantitative in vitro assay for detection of human IgG-class antibodies to diphtheria toxoid. The test kit contains reagent wells coated with diphtheria toxoid. In the first reaction step, diluted patient samples are incubated in the wells. In the case of positive samples, specific IgG antibodies will bind to the antigens. To detect the bound antibodies, a second incubation is carried out using an enzyme-labelled antihuman IgG (enzyme conjugate) catalyzing a color reaction. (Package insert: Anti-Diphtheria Toxoid ELISA [IgG] Test Instructions, EUROIMMUN US; 09/13/2017)

PDF Report
No

Specimen Retention Time
14 days

Performing Laboratory Location
Rochester

Fees & Codes

Test Classification
This test was developed, and its performance characteristics determined by Mayo Clinic in a manner consistent with CLIA requirements. This test has not been cleared or approved by the US Food and Drug Administration.

CPT Code Information
86317

LOINC® Information

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<th>Test Order Name</th>
<th>Order LOINC Value</th>
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<tr>
<td>DIPGS</td>
<td>Diphtheria Toxoid IgG Ab, S</td>
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<table>
<thead>
<tr>
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<td>Diphtheria IgG Ab</td>
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<tr>
<td>DEXDP</td>
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